

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Claims 9, 11, 29 and 30 were rejected under 35 USC § 112, first paragraph, as claiming new matter. The Examiner questions the support for the activation stimulus consisting of “mature dendritic cells.” In response, Applicants point out that the specification in point (10) on page 4 of the specification teaches the activating/stimulating/expanding agent may comprise antigen presenting cells generally, preferably immature or mature dendritic cells broadly. Consequently, Applicants do not believe that the previous amendments introduce new matter. An early notice to that effect is earnestly solicited.

Claims 9, 11, 29 and 30 were rejected under 35 USC § 112, first paragraph, as being broader than the enabling disclosure. The Examiner finds that it would require undue experimentation to produce Tr1 regulatory T cells with an anergic state inducing agent “consisting of” CD4⁺CD25⁺ T cells, as claimed. While Applicants respectfully disagree, in order to advance the prosecution, Applicants have amended the claims above without prejudice to require that the anergic state inducing agent consists not only of the activated CD4⁺CD25⁺ T cells, but also of an activation stimulus that consists of at least one of: (a) plate-bound anti-CD3 and soluble anti-CD28 antibodies; and (b) mature dendritic cells. The Examiner concedes the specification teaches the activation stimulus consisting of (a) plate-bound anti-CD3 and soluble anti-CD28 antibodies; or (b) mature *allogenic* dendritic cells. The specification teaching of (a) and (b) provides representative support

for use alone or in combination and, therefore, supports “at least one of (a) and (b),” now claimed. Further, the specification in point (10) on page 4 of the specification teaches the activating/stimulating/expanding agent may comprise antigen presenting cells generally, preferably immature or mature dendritic cells broadly. Consequently, Applicants do not believe that the amendments above introduce new matter. An early notice to that effect is earnestly solicited.

Further, the Examiner has alleged that syngeneic dendritic cells do not activate T cells unless they have been loaded with an exogenous antigen for which the T cells are specific. However, Applicants respectfully submit that at the time the present invention was made, it was well known in the art that both allogenic and syngeneic mature dendritic cells were capable of directly stimulating T cells. In support, Applicants direct the Examiner’s attention to the Reeves reference cited in the accompanying information disclosure statement, particularly to the left-hand column on page 5675 and Table 3. There, Reeves, which was published in 1996, and, therefore, represents the state of the art, demonstrates stimulation of T cells with syngeneic (autologous) DCs, thereby proving that persons skilled in the art were aware of the use of syngeneic DCs to stimulate T cells at the time the present invention was made.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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